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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,111	03/10/2004	Dario Norberto R. Carrara	88066-7900	5916

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PATENT DEPARTMENT
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EXAMINER	
SCHLIENTZ, NATHAN W	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
06/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@winston.com
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Advisory Action Before the Filing of an Appeal Brief	**Application No.**	**Applicant(s)**
	10/798,111	CARRARA ET AL.
	Examiner	**Art Unit**
	Nathan W. Schlientz	1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 June 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-5,7,11,13,17-19,29,37,40-42,46,56-58,60-63 and 67-72*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/John Pak/
Primary Examiner, Art Unit 1616

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1, 3-5, 7, 11, 13, 17-19 ,29, 37, 40-42, 46 ,56-58 ,60-63 and 67-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (WO 02/22132; US 7,030,104; and US 2003/0181430), in view of Dudley et al. (US 6,503,894) and Wang et al. (The Journal of Clinical Endocrinology and Metabolism, 2000) for the reasons of record.

Applicant argues on page 10 that there is no teaching or suggestion in either the Dudley et al. or Wang et al. reference to motivate a person of ordinary skill in the art to replace the active agents in the composition of Gray et al. with an androgenic or anaboic steroid disclosed in Dudley.

However, the examiner respectfully asserts that both Gray et al. and Dudley et al. teach that percutaneous administration of hormones is beneficial and overcomes certain drawbacks associated with other forms of administration. Gray et al. teach percutaneous administration of progestogen and estrogen, together with an alcohol, polyalcohol, water and absorption promoting agent overcomes drawbacks associated with oral routes of administration. Dudley et al. teach percutaneous administration of an active pharmaceutical ingredient, such as an anabolic steroid, androgenic steroid, or progestogen, together with a lower alcohol, a penetration enhancing agent, a thickener, and water overcomes drawbacks associated with intramuscular injections, oral replacement, subdermal pellet implants, and transdermal patches. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in substituting testosterone in the place of the progestogens in the compositions of Gray et al. for percutaneous administration in view of the teachings of both Gray et al. and Dudley et al. that percutaneous administration of hormones, such as estrogen, progestogen, and testosterone, overcomes drawbacks associated with other forms of administration.

Applicant further argues on page 10 that Table 1 of Gray et al. does not teach the relationships or amounts for the components to arrive at what is presently claimed. The examiner respectfully asserts that formulations G29-287, G29-299 and Tx11323 batch-12 as shown in Table 1 contains 0.1, 0.4 or 0.5% hormone (NAc and/or Estradiol), 0.5% Carbopol, 6% Propyleneglycol, 5% Transcutol (i.e., ratio of propyleneglycol to Transctuol of 1.2:1 (6:5), and total combined amount 11%), 0.05% EDTA, 0.3% Triethanolamine, 45% Ethanol, and the remainder is water. Therefore, formulations G29-287, G29-299 and Tx11323 batch-12 clearly contain an alkanol, polyalcohol, and permeation enhancer in amounts that fall within the instantly claimed ranges.

Applicant also argues that Gray et al. teach numerous other embodiments, and it becomes necessary to consider in which of the numerous formulations of Gray et al. would testosterone be substituted in place of the active agents taught by Gray et al. The examiner respectfully argues that the teaching of Gray et al. is not limited to the preferred embodiments, but rather is relevant for all that it would have taught one of ordinary skill in the art. Gray et al. clearly teach that diethylene glycol monoethyl ether (Transcutol) is a suitable absorption promoting agent for use in their compositions, and further teaches formulations comprising Transctuol as the permeation enhancer. As noted by applicant, Gray et al. teach that two pairs of solvents, propylene-glycol/Transcutol and propylene-glycol/Solketal, are suitable for obtaining the promoter effect. Therefore, one of ordinary skill in the art would have a reasonable expectation of success in using the compositions according ot Gray et al. that comprise Transcutol.

Applicant further argues on page 11 that Gray et al. teach that in order to ensure a complete therapeutic effect in all women it would be worthwhile to obtain higher circulating levels of nomegestrol acetate and that the results of diffusion in vitro were improved by other formulations. Applicant argues that Gray et al. teach that formulation G42-120 is the most preferred and a person of ordinary skill in the art would have chosen that formulation for substituting testosterone.

The examiner respectfully argues that Gray et al. teach that gel Tx11323, which uses Transcutol, applied at a rate of 3 g of gel on a body area of 400 cm2 leads to plasmatic levels of estradiol at the equilibrium of approximately 40 pg/ml, which are located in the area of effective plasmatic concentrations of estradiol as these are comprised between 30 and 60 ng/ml (col. 14, ln. 1-6). Therefore, Gray et al. teach that Tx11323 resulted in effective plasmatic levels. Thus, one of ordinary skill in the art would have a reasonable expectation of success in substituting testosterone in this composition. Again, Gray et al. is not limited to the preferred embodiments, but rather is relevant for all that it would have taught a person having ordinary skill in the art.

Applicant then argues on page 12 that testosterone is a different active than progestogen and estradiol which perform differently even if used with similar solvents. However, the examiner respectfully argues that Dudley et al. teach compositions comprising testosterone for percutaneous administration wherein the penetration enhancer can include diethylene glycol monomethyl ether. Therefore, one of ordinary skill in the art would have a reasonable expectation that using testosterone in the formulations of Gray et al. which comprise Transcutol will be effective when administered percutaneously.